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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,607	12/08/2000	Giulio Tononi	P-NI 4447	4199

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/05/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,607

Applicant(s)

TONONI ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 10, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1647

The examiner in charge of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Sandra Wegert in Group Art Unit 1647.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application before an examination or first action on the merits. The RCE is therefore improper and has been *withdrawn*. An action on the merits follows.

The Information Disclosure Statement filed 1/19/01, the Information Disclosure Statement filed 10/15/01 and the Information Disclosure Statement filed 3/19/02 have been entered into the record. Applicant's election of Group IV, Claims 12 and 13 without traverse in Paper 11 (3/5/02) is acknowledged. Likewise, Applicant elected the gene product *BiP* for prosecution. Applicant's election with traverse of *BiP* is acknowledged. The traversal is on the grounds that *BiP* and the other recited proteins in claims 12 and 13 are related as species, and that furthermore it would not constitute an undue burden to examine all the gene products recited. However, *BiP* and the other recited proteins were properly restricted as distinct products having vastly different functions. Furthermore, it would constitute an undue burden to search all recited gene products and relate each to a disorder of arousal, circadian rhythm or "vigilance".

Art Unit: 1647

Claims 12 and 13, as reciting *BiP* protein, are under examination in the instant application.

Informalities

The specification is objected to for the following informalities:

Information Disclosure Statements

The Information Disclosure Statement filed in Paper No. 3 (1/19/01) fails to comply with the provisions of MPEP § 609 because: References 60-100 have no author or date.

Appropriate correction is required.

Claim Objections/Rejections

Claim Objections

Claims 12 and 13 are objected to because they recite or encompass non-elected inventions.

Claim Rejections

35 USC § 112, first paragraph-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of determining the efficacy of a compound in modulating the levels of waking/resting activity levels in flies deficient in dopamine acetyltransferase, does not reasonably provide enablement for a method of determining the efficacy of a compound in ameliorating a *vigilance* disorder in individuals that may include mammals or humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are directed to a method of determining the efficacy of a compound in ameliorating a vigilance disorder in individuals, including mammals or humans, by measuring gene expression of genes and gene products that have been determined to possess diurnal expression levels in *Drosophila* (e.g., expressed during the day or night). The claims do not recite a particular vigilance disorder, although the specification seems to indicate that a vigilance disorder is a deviation from normal in the activity levels and especially the rebound activity levels of normal and DAT^{lo} mutant flies. The specification discloses: methods of measuring activity levels of flies; a mutant fly with a diminished dopamine acetyltransferase enzyme that displays greater rebound *rest* behavior than normal flies; and changes in expression levels of several genes in resting, awake and rest-deprived flies and rats. The scope of the patent

Art Unit: 1647

protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 12 and 13 are rejected since they recite a method of determining the efficacy of compounds that ameliorate a vigilance disorder. However, the breadth of the claims is too extensive. Applicants are not enabled for determining the efficacy of compounds in ameliorating a vigilance disorder without defining and narrowing the disorder and precisely associating it with a particular gene expression profile. Applicants have not provided guidance or working examples with regard to how to define a vigilance disorder based on activity patterns of flies nor on gene expression. Nor is it predictable or obvious to one of ordinary skill in the art what that disorder might be and how it is related to gene expression. A large quantity of experimentation is required to relate the activity levels of normal and DAT¹⁰ *Drosophila* to a disorder of the sleep/wake cycle in mammals and to evaluate compounds that might ameliorate a disorder based on gene expression of the selected genes. Lastly, the nature of the invention is complex, especially given the intricacies and lack of predictability concerning interactions between complex behaviors such as "vigilance" and expression of some nuclear binding proteins, enzymes, receptors and their specific binding partners.

Therefore, due to the large breadth of the claims regarding: methods of determining the efficacy of compounds to be used to ameliorate *all* vigilance disorders; the lack of guidance and working examples of how to find compounds that ameliorate vigilance disorders; the lack of guidance in administering such a compound; the lack of a clear association between a gene expression profile and a vigilance disorder; as well as the unpredictability in the art of how to detect and ameliorate a vigilance disorder- the Examiner has determined that undue experimentation would be necessary to practice the methods of finding compounds that modulate vigilance disorders as claimed.

Claim Rejections - 35 USC § 112, second paragraph, indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, -second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite a "vigilance" disorder and a "vigilance" gene. However, one skilled in the art cannot determine the metes and bounds of the claimed invention because the vigilance disorder and the vigilance genes cited in the claims are not defined in the specification. And, since behavioral disorders are very complicated, and probably involve numerous genes, the relationship between and among gene expression, the behaviors described and "vigilance" are not obvious.

Art Unit: 1647

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623. Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
11/3/02

Gary L. Kunz
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